1. (Original) A process for preparing an uncoated sumatriptan tablet for oral administration, the process comprising the steps of:

granulating sumatriptan or a pharmaceutically acceptable salt with one or more diluents and/or binders to form granules;

mixing the granules with one or more pharmaceutically acceptable excipients to form a mixture; and

compressing the mixture to form a tablet.

2. (Original The process according to claim 1, further comprising wax polishing the tablet.

3. (Original) The process according to claim 1, wherein granulating comprises dry mixing the one or more diluents and/or binders with sumatriptan and granulating with an aqueous and/or a non-aqueous solvent.

4. Cancelled

5. Cancelled

6. Cancelled

7. (Original) The process according to claim 1, wherein the pharmaceutically acceptable salt comprises one or more of hydrochloride, hydrobromide, sulphate, nitrate, phosphate, formate, mesylate, citrate, benzoate, fumarate, maleate, tartrate and succinate salts.

8. Cancelled

9. (Original) The process according to claim 1, wherein the one or more diluents comprises one or more of calcium carbonate, calcium phosphate-dibasic, calcium phosphate-tribasic, calcium sulfate, cellulose-microcrystalline, cellulose powdered, dextrates, dextrins, dextrose excipients, fructose, kaolin, lactitol, lactose, mannitol,

sorbitol, starch, starch pregelatinized, sucrose, sugar compressible, and sugar confectioners.

10. Cancelled

11. (Original) The process according to claim 1, wherein the binder comprises one or more of methyl cellulose, hydroxypropyl cellulose, hydroxypropyl methyl cellulose, polyvinylpyrrolidone, gelatin, gum arabic, ethyl cellulose, polyvinyl alcohol, pullulan, pregelatinized starch, agar, tragacanth, sodium alginate, propylene glycol, and alginate.

12. Cancelled

13. (Original) The process according to claim 1, wherein the pharmaceutically acceptable excipient comprises one or more of diluents, binders, disintegrants, lubricants, coloring agents, and flavoring agents.

14. Cancelled.

15. Cancelled

16. Cancelled

17. Cancelled

18. Cancelled

19. Cancelled

20. (Original) The process according to claim 2, wherein wax material comprises one or more of shellac, modified shellac, opaglos II, carnuba wax, bees wax, paraffin wax, and polyethylene glycol.

21. Cancelled

22. (Original) The process according to claim 2, wherein the total weight build up of wax polishing solid comprises up to about 10% w/w, based on the total weight of the tablet.

23. (Original) The process according to claim 1, further comprising granulating and/or mixing a second active pharmaceutical ingredient with the sumatriptan.

24. (Original) A process for preparing uncoated sumatriptan tablets for oral administration, the process comprising the steps of:

spraying a solution or suspension of sumatriptan or a pharmaceutically acceptable salt in a solvent onto inert cores to form a first layer;

blending the core having the first layer with one or more pharmaceutically acceptable excipients to form a blend; and

compressing the blend to form a tablet.

25. (Original) The process of claim 24, wherein the solution or suspension of sumatriptan in a solvent further includes one or more diluents and/or binders.

26. (Original) The process of claim 24, further comprising creating a second layer on the cores having the first layer, the second layer comprising one or more diluents and/or binders.

27. (Original) The process of claim 25, further comprising creating a second layer on the cores having the first layer, the second layer comprising one or more diluents and/or binders.

28. (Original) The process of claim 24, further comprising polishing the tablet.

29. Cancelled

30. Cancelled

31. Cancelled

32. Cancelled

33. Cancelled

34. Cancelled

35. Cancelled

36. (Original) The process according to claim 24, further comprising spraying and/or blending a second active pharmaceutical ingredient with the sumatriptan.

37. (Original) A wax polished dosage form of sumatriptan, the dosage form comprising:

sumatriptan or a pharmaceutically acceptable salt;

one or more pharmaceutically acceptable carriers or excipients; and

a wax polish on the dosage form.

38. Cancelled

39. Cancelled

40. (Original) The wax polished dosage form of sumatriptan of claim 37, wherein the total weight buildup of wax material is up to 10% w/w, based on the weight of tablet.

41. Cancelled

42. Cancelled

43. Cancelled

44. (Original) The wax polished dosage form of sumatriptan of claim 37, further comprising a second active pharmaceutical ingredient in the dosage form.

45. (Original) An uncoated, wax polished sumatriptan tablet comprising:

a tablet core comprising about 10-200 mg of sumatriptan or a physiologically acceptable salt and one or more pharmaceutically acceptable carriers or excipients, and

a wax polish on the tablet core,

wherein the wax polish comprises an amount of from about 2 to 10% weight/weight of the tablet.

46. (Original) An uncoated, taste-masked sumatriptan tablet for oral administration, the uncoated tablet comprising:

an intragranular portion comprising granules of sumatriptan or a pharmaceutically acceptable salt and one or more diluents and/or binders present in a sufficient amount to cause taste-masking of the sumatriptan or pharmaceutically acceptable salt; and

an extragranular portion comprising one or more pharmaceutically acceptable excipients around the intragranular granules.

47. (Original) The uncoated, taste-masked sumatriptan tablet of claim 46, wherein the one or more diluents and/or binders in the intragranular portion completely encapsulate the sumatriptan or physiologically acceptable salt.

48. (Original) The uncoated, taste-masked sumatriptan tablet of claim 46, wherein the one or more diluents and/or binders in the intragranular portion substantially encapsulate the sumatriptan or physiologically acceptable salt.

49. (Original) The uncoated, taste-masked sumatriptan tablet of claim 46, wherein the intragranular portion and/or the extragranular portion further comprises a second active pharmaceutical ingredient.

50. (Original) A method of treating or prophylactically treating a human suffering from a migraine condition, the method comprising orally administering a wax polished dosage form of sumatriptan, the oral dosage form comprising:

sumatriptan or a physiologically acceptable salt and a pharmaceutically acceptable carrier or excipient;

one or more pharmaceutically acceptable carriers or excipients; and

a wax polish on the dosage form.

51. (Original) The method of treating of claim 50, wherein the tablet comprises about 10 mg to 200 mg of sumatriptan.

52. (Original) A method of treating or prophylactically treating a human suffering from a migraine condition, the method comprising orally administering an uncoated, taste-masked tablet of sumatriptan, the uncoated tablet comprising:

an intragranular portion comprising granules of sumatriptan or a pharmaceutically acceptable salt and one or more diluents and/or binders present in a sufficient amount to cause taste-masking of the sumatriptan or pharmaceutically acceptable salt; and

an extragranular portion comprising one or more pharmaceutically acceptable excipients around the intragranular granules.

53. (Original) The method of treating of claim 52, wherein the tablet comprises about 10 mg to 200 mg of sumatriptan.

54. (Original) The method of treating of claim 52, wherein the intragranular portion and/or the extragranular portion further comprises a second active pharmaceutical ingredient.

Entry of this Preliminary Amendment before the calculation of the fees and examination is respectfully requested.

Respectfully submitted,
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